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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,113	02/03/2006	Valery Khazhmuratovich Zhilov	4874-7001	2931
27123 7590 01/07/2008 MORGAN & FINNEGAN, L.L.P. 3 WORLD FINANCIAL CENTER NEW YORK, NY 10281-2101			EXAMINER LEWIS, PATRICK T	
			ART UNIT	PAPER NUMBER
			1623	
			NOTIFICATION DATE	DELIVERY MODE
			01/07/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTOPatentCommunications@Morganfinnegan.com
Shopkins@Morganfinnegan.com
jmedina@Morganfinnegan.com

Office Action Summary

Application No.

10/567,113

Applicant(s)

ZHILOV ET AL.

Examiner

Patrick T. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☒ Claim(s) 10-42 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date See Continuation Sheet.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :03292007; 11022006; 08092006; 02032006.

DETAILED ACTION

Claim Objections

1. Claims 10-42 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and/or cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 10-42 have not been further treated on the merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Variables A, B and Z are not clearly set forth in the claim.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yurgi et al. Chem. Pharm. Bull. (1972) Vol. 20, pages 1513-1521 (Yurgi), Zyczynska-Baloniak et al. Polish Journal of Chemistry (1978), Vol. 52, pages 2461-2465 (Zyczynska), Zhilov WO 02/09681 (Zhilov), and el Kouni et al. US 5,476,855 (Kouni) in combination.

Claims 1-9 are drawn to a cyclic bioisostere of derivatives of a purine system.

Yurgi teaches 2-substituted-5,6,7,8-tetrahydropyrimido[4,5-d]pyridazine-5,8-diones (6) having a variety of substituents at 2-position (page 1513; Table II). Among tetraazanaphthalene derivatives a number of pharmacologically active compounds have

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been known. Yurgi is interested in the syntheses of the pyridazine-containing tri- and tetraazanaphthalene derivatives to test their pharmacological activities because 1-hydrazinophthalazine is well known as a hypotensive agent.

Zyczynska teaches the synthesis of 4-hydroxypyrazine-[2,3-d]-pyridazine-1-one (1) (page 2461). The bicyclic system of pyrazinepyridazine does not occur in natural substances. Its derivatives have been synthesized during the last twenty years. It has been shown that derivatives of quinoxaline pyridazinedione, of quinoxaline pyridazine possess tuberculostatic activity.

Zhilov teaches a large group of pharmacologically adequate salts of amino-derivatives of 2,3-dihydrophthalazine-1,4-dione which can be used for preventing and treatment of various diseases associated with immunopathologic changes (pages 1-2).

Yurgi, Zyczynska and Zhilov do not teach the instant compounds wherein variable R is a ribose moiety. Zhilov however does teach pharmacologically acceptable salts.

Kouni teaches that nucleobases and nucleosides are widely used as chemotherapeutic agents for cancer and for viral, fungal, bacterial and parasitic infections. Most pyrimidine analogs used in cancer chemotherapy must be converted to the nucleoside 5'-monophosphate level before any anticancer activity can be realized. However, almost all are administered as nucleosides or bases to facilitate transport into cells.

Although Yurgi, Zyczynska and Zhilov do not teach the instant compounds wherein variable R is a ribose moiety, to do so would have been obvious to one of

ordinary skill in the art at the time of the invention. As shown by Kouni, it is usually the nucleoside 5'-monophosphate that demonstrates pharmacological activity; however, it would have been obvious to one of ordinary skill in the art to administer the compounds as nucleosides or bases to facilitate transport into cells. The attachment of nucleobases to ribose moieties to form nucleosides was routine at the time of the invention. One would have been motivated to do so in order to maximize the pharmacological effect. It would have also been obvious to produce pharmaceutically acceptable salts as taught by Zhilov. In the instant case, combining prior art elements according to known methods to yield predictable result renders the instant invention obvious.

Conclusion

8. Claims 1-42 are pending. Claims 1-9 are rejected. Claims 10-42 are objected to. No claims are allowed.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday 10 am to 3 pm (Maxi Flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Dr. Patrick T. Lewis
Primary Examiner
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ptl